

Economic Impact Statement
LSA Document #20-311

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

The Indiana State Department of Health (ISDH) is seeking to amend [410 IAC 3-3-3](#) to update and add to the list of disorders all newborns and infants shall be screened for, [410 IAC 3-3-3.5](#) to set standards for pulse oximetry screenings, and [410 IAC 3-3-13](#) to increase the fee charged for newborn screenings to cover the cost of screening for new disorders.

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

[IC 5-28-2-6](#) defines a small business as a business entity that satisfies the following requirements: (1) On at least fifty percent (50%) of the working days of the business entity occurring during the proceeding calendar year, the business entity employed not more than one hundred fifty (150) employees. (2) The majority of the employees of the business entity work in Indiana.

There are approximately seven (7) licensed birthing centers that are subject to the rule. The eighty-six (86) Indiana hospitals that deliver babies, which are subject to this rule, do not meet the definition of a small business.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed rule amendment will not impact any reporting, record keeping, or other administrative costs for small businesses. The updates to pulse oximetry screening do not impact the timeframe or process for referring an infant for additional screening or echocardiogram diagnostic testing if the infant fails the initial pulse oximetry screen. Birthing centers are only permitted to deliver a normal or uncomplicated pregnancy. Therefore, if a pregnant patient or infant is diagnosed prenatally with a medical condition, the delivery and any necessary treatment or procedures postnatally would occur at a hospital. The updates also reiterate that pulse oximetry screen information should be completed on the newborn's screening card; however, that information is already required to be submitted by birthing centers and hospitals. Therefore, these changes should not make a difference in how small businesses will comply with newborn screening requirements.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

Compliance with the proposed rule amendment imposes no economic impact on small businesses. The seven (7) licensed birthing centers are the only "small businesses" subject to the rule. Adding three (3) new conditions and updating the pulse oximetry rule to allow for exemptions and changing the standards for evaluating a failed screen should not have a fiscal impact on a birthing center, since these changes do not impact the timeframe or process for referring an infant for additional testing or treatment if the infant fails the pulse oximetry screen conducted by the birth center.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt the rule; or any other state or federal law.

The proposed rule amendment imposes no cost on small businesses.

5. Regulatory Flexibility Analysis.

No regulatory flexibility analysis is necessary because the proposed rule amendment imposes no costs on small businesses.

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